

**LAURAIN DEWALD Anterior Fixation System**  
**510(k) Summary**  
**December 2002**

DEC 13 2002

**I. Company: Medtronic Sofamor Danek**  
**1800 Pyramid Place**  
**Memphis, TN 38132**  
**(901) 396-3133**

**II. Proprietary Trade Name: LAURAIN DEWALD Anterior Fixation System**

**III. Regulation Number: 888.3060 - KWQ**

**IV. Product Description**

The LAURAIN DEWALD Anterior Fixation System consists of a variety of shapes and sizes of plates, screws, nuts, spacers and staples, as well as ancillary products and instrument sets. The components can be locked into a variety of configurations, with each construct tailor-made for the individual case.

The purpose of this submission is to include additional plates, screws and staples to the LAURAIN DEWALD Anterior Fixation System.

**V. Indications**

Properly used, the LAURAIN DEWALD™ Anterior Fixation System is intended to provide stabilization during the development of a solid spinal fusion. The specific indications are: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) pseudoarthrosis, (3) spondylolysis, (4) spinal deformation such as kyphosis and lordosis, (5) fracture, (6) unsuccessful previous attempts at spinal surgery, (7) tumor resection, (8) correction of severe instability and/or deformity when used in addition to a posterior spinal instrumentation system, (9) neoplastic disease, and/or (10) deformity associated with deficient posterior elements, such as laminectomy, spina bifida, or myelomeningocele.

**VI. Substantial Equivalence**

Documentation was provided which demonstrated the LAURAIN DEWALD Anterior Fixation System to be substantially equivalent to itself.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 13 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Richard Treharne, Ph.D.  
Senior Vice President, Regulatory Affairs  
Medtronic Sofamor Danek  
1800 Pyramid Place  
Memphis, Tennessee 38132

Re: K023797  
Trade Name: LAURAIN DEWALD Anterior Fixation System  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal Intervertebral Body Fixation Orthosis  
Regulatory Class: II  
Product Code: KWP  
Dated: November 13, 2002  
Received: November 14, 2002

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

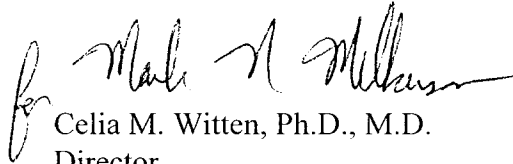
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Richard W. Treharne, Ph.D.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized "for" written to the left of the main signature.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K023797Device Name: LAURAIN DEWALD Anterior Fixation System**Indications for Use:**

Properly used, the LAURAIN DEWALD™ Anterior Fixation System is intended to provide stabilization during the development of a solid spinal fusion. The specific indications are: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) pseudoarthrosis, (3) spondylolysis, (4) spinal deformation such as kyphosis and lordosis, (5) fracture, (6) unsuccessful previous attempts at spinal surgery, (7) tumor resection, (8) correction of severe instability and/or deformity when used in addition to a posterior spinal instrumentation system, (9) neoplastic disease, and/or (10) deformity associated with deficient posterior elements, such as laminectomy, spina bifida, or myelomeningocele.

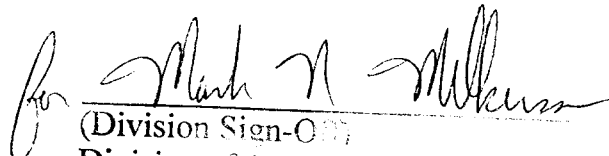
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Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)  
(Optional 1-2-96)

OR

Over-the-counter Use \_\_\_\_\_

  
(Division Sign-Off)  
Division of Cerebral, Restorative  
and Neurological Devices

510(k) Number K023797